

Assessment of Research Gaps in Healthcare Worker PPE

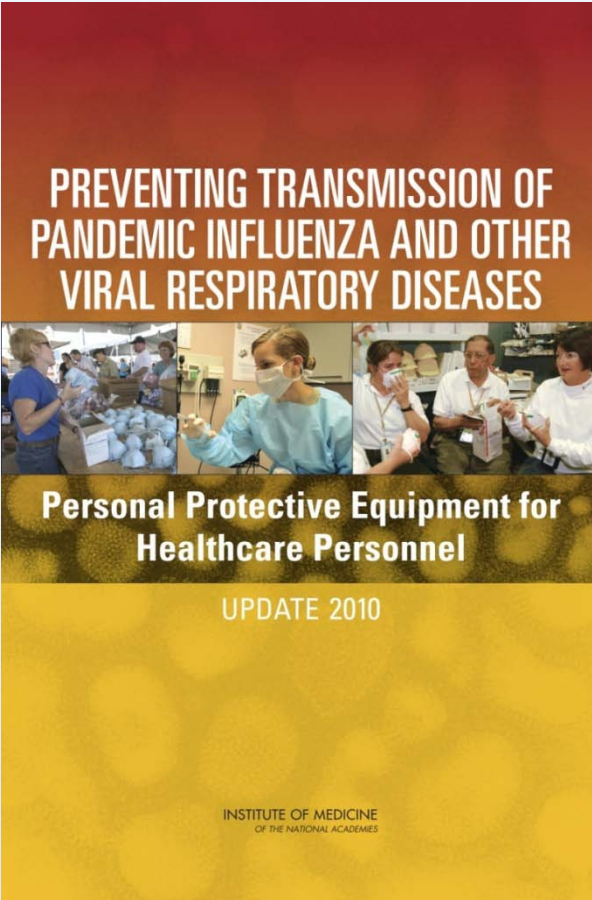
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Project Goal

Better understand research gaps in healthcare worker (HCW) personal protective equipment (PPE) to determine the focus of possible future NPPTL research

Background

- PPE is a critical component in the hierarchy of controls used to protect HCW from infectious hazards.
- HCW PPE may include gowns, respirators, face masks, gloves, eye protection, face shields, and head & shoe coverings.
- Institute of Medicine’s (IOM) recent reports and NPPTL Implementation Plan highlight the need for more research on HCW PPE.
- Important research has been conducted in certain areas, such as respirators, masks, and gloves but studies in other areas, particularly gowns, drapes are scarce. This research will initially focus on gowns & drapes.
- Understanding the issues related to the design and development of gowns & drapes, as well as the factors that impact their use, such as barrier effectiveness, comfort, cost, durability, testing, standards, maintenance, care, and awareness, are critical to ensuring HCW’s are adequately protected.



IOM Report, Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel Update 2010

Methods

- Literature review
- Informal meetings with Association for the Advancement of Medical Instrumentation (AAMI), ASTM F23 Committee, HCW’s, industry experts
- Participation in AAMI Protective Barriers, ASTM F 23, and American Association of Textile Chemists and Colorists (AATCC) committees

Results

Existing Regulations, Standards & Guidelines

- FDA clears some types of PPE for sale as medical devices. The approval process relies on determining equivalence to predicate devices and requires manufacturer/supplier declaration of conformity, except for respirators which require NIOSH approval.

Results-Con’t

Existing Regulations, Standards & Guidelines - Con’t

FDA Classification of PPE-Related Equipment			
Class	Risk to Patient or Device Wearer	Requirements	Healthcare PPE and Related Devices ^(*)
I	Low	General standards for good manufacturing processes; most Class I devices are exempt from 510k submissions	• Surgeons’ gloves (510k required) • Examination gloves (510 k required) • Other surgical apparel (isolation gowns, shoe covers, caps, hoods, operating room shoes) (510k exempt)
II	Intermediate	510k submission	• Surgical gowns • Surgical masks • Surgical respirators

^(*) Protective eyewear used as PPE is not regulated by the FDA as a medical device

Existing standards and guidelines for surgical gowns and drapes are listed below:

Organization	Standard
ASTM	F1670 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood F1671 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System F2407 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities
AAMI	TIR No.11 Selection & Use of Protective Apparel & Surgical Drapes in Health Care Facilities ANSI/ AAMI PB70 Liquid Barrier Performance & Classification of Protective Apparel & Drapes Intended for Use in Health Care Facilities AAMI/ANSI ST65 Processing of Reusable Surgical Textiles for Use in Health Care Facilities
NFPA	702 Standard for Classification of Flammability of Wearing Apparel 1999 Standard on Protective Clothing for Emergency Medical Operations
AORN	Recommended Practices for Selection and Use of Surgical Gowns & Drapes

PPE Selection & Use

According to the 2010 IOM report, HCW PPE should:

- Effectively reduce risks of disease or injury
- Be practical regarding issues of cost, time, and training
- Be appropriate to the occupational risk being encountered
- Minimize negative interactions with or effects on patients and their families & caregivers
- Be acceptable and usable by HCW in their daily tasks (including ease of communication & comfort)

Disclaimer: The findings and conclusions in this poster have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

Results-Con’t

PPE Selection & Use - Con’t

Association of periOperative Registered Nurses (AORN) Guidelines for selection of surgical gown & drapes include information on:

- Barrier Performance & Integrity
- Linting
- Flammability
- Comfort



Barriers to Proper PPE Use

- Limited involvement of HCW’s in the selection process
- Dominant factor in sales of surgical apparel is price
- Wrong PPE selection for high-fluid procedures
- Limited or no availability of correct PPE for certain procedures
- Limited knowledge about the differences in garments

Conclusions/ Future Work

Numerous research gaps were identified:

- Lack of awareness regarding standards & classifications of PPE
- Test Procedures & standards do not match HCW expectations or needs
- Research on evidence-based performance requirements for PPE
- Clinical research that evaluates the use, effectiveness, and failures of HCW PPE
- Innovation in gown design & engineering (with particular attention to interfaces, repellant finishes, fabric technology, functionality, wearability, and other factors)
- In-depth analysis of level of protection & cost effectiveness of single-use vs. reusable PPE
- Determination of the role of PPE in reducing the transmission of diseases
- Identifying clinical situations that require certain types of gowns or other PPE
- Identifying the physiological impact of PPE



Next Step: From the list of research gaps, identify priority projects most suitable for future NPPTL research.